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Stephen Nicholas Princeas

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EXAMINER

YOUNG, RACHEL T

ART UNIT

PAPER NUMBER

3771

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/599,244	PRINEAS, STEPHEN NICHOLAS	
	<b>Examiner</b>	<b>Art Unit</b>	
	RACHEL YOUNG	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 5) ☒ Claim(s) 1-29 is/are pending in the application.
- 5a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 6) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 7) ☒ Claim(s) 1-29 is/are rejected.
- 8) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 9) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/22/06</u> .   | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

### ***Claim Objections***

1. Claims 1, 2, 20, 21 and 24 are objected to because of the following informalities:  
Claim 1, recites "a frst opening" on line 13, which should be corrected to --a first opening--. Claim 2, ll. 5 recites "ta a location", which should be corrected to --to a location--. Claim 20, ll. 2 have run way in quotes, which it should not. Claim 21, ll. 2 recites "fkom", which should be corrected to --from--. Claim 24, ll. 3 recites "insat", which should be corrected to --insert--. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:  

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 3, ll. 2 recites "the leading edge", which lacks proper antecedent basis. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claim 13 is rejected under 35 U.S.C. 102(e) as being anticipated by Friedman et al. (2004/0073088).

Regarding claim 13, Friedman discloses an oropharyngeal airway device (fig. 2 and 10) that is configured to include internal markings (Page 3, para 30, ll. 13-17, Page 6, para 61) for the purpose of guiding an endoscope there through.

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1, 4-10, 12 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berman (4,069,820) in view of Elam (4,449,526).

Regarding claim 1, in fig. 15 and 17 Berman discloses a unitary tube 10b having a passage there through; a locating flange 12b provided at a proximal end of a first portion of the tube to form, in combination with the first portion, at least part of a mouthpiece (fig. 32, Col. 4, ll. 5-9) defining an inlet to the passage, the flange adapted to locate adjacent an outer surface of the patient's mouth when the first portion of the tube extends into the mouth cavity (fig. 32), the tube having a second portion extending

from the first portion, the second portion having a distal end which defines an outlet to the tube and which is adapted to extend to a location closely adjacent the base of the tongue (fig. 32), the outlet at the distal end of the tube is defined by a first opening (outlet at distal end) that is configured to align with the opening to the larynx. Berman is silent regarding that a posterior surface of the second portion of the tube includes a second opening adapted to align with the junction of the nasopharynx with the oropharynx. However, in fig. 10 Elam teaches an oropharyngeal airway with a posterior surface of a second portion having a second opening 74. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Berman's posterior surface of a second portion with a second opening, as taught by Elam, for the purpose of allowing for the passage of a sump tube into the esophagus (Col. 5, ll. 53-59), the suctioning of mucus and nasal intubation (Col. 6, ll. 62-Col. 7, ll. 11).

Regarding claim 4, the modified Berman discloses that the second opening has a fusiform profile (Fig. 6D Elam).

Regarding claim 5, the modified Berman discloses that the second posterior opening is fully surrounded by the tube material (Fig. 6D Elam).

Regarding claim 6, the modified Berman discloses a resiliently openable split type formation (24b, fig. 23, fig. 17 Berman) along the side of the tube, but is silent regarding that the slit is along the posterior side of the tube. However, it would have been an obvious design consideration to modify the modified Berman's side slit with a posterior split because it appears that the location of the split has no criticality and that a posterior split would perform equally as well as a side split at allowing for an

endotracheal tube and other medical device to be inserted into the oropharyngeal airway. The modified Berman discloses that the second posterior opening includes a resiliently openable split type formation that extends from the second posterior opening to the distal end of the tube.

Regarding claim 7, the modified Berman discloses that the edges of the split type formation are tapered obliquely (Fig. 17 and 23 Berman).

Regarding claim 8, the modified Berman discloses that the distal end of the tube also includes a protuberance (14d, fig. 32 Berman) configured to locate the device by engagement in the vallecula between the epiglottis and the back of the tongue.

Regarding claim 9, the modified Berman discloses that the distal end of the tube also includes a protuberance (14b, fig. 32 Berman) configured to locate the device by engagement in the vallecula between the epiglottis and the back of the tongue and the leading edge of the first opening forms the locating protuberance (fig. 32 Berman).

Regarding claim 10, the modified Berman discloses that the leading edge is rounded (14d, fig. 32 Berman).

Regarding claim 12, the modified Berman discloses that the external wall of the tube is rectangular in cross section (Fig. 23) and is silent regarding a generally elliptical cross-section. However, Berman discloses an alternate embodiment in fig. 7 having a generally elliptical when viewed in transverse cross-section. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Berman's cross section with an elliptical cross-section, as disclosed by Berman, for the purpose of providing comfort to a patient.

Regarding claim 25, the modified Berman discloses that the flange of the mouthpiece is formed integral with the tube (Fig. 15 and 17, Berman).

8. Claims 2-3 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berman/Elam, as applied to claim 1 above, in further view of Baildon (4,919,126).

Regarding claims 2 and 11, the modified Berman discloses a first portion that is substantially straight (Fig. 15 Berman) and the second portion being of an arcuate form (fig. 15 Berman), but is silent regarding that the tube is generally hook shaped with the second portion extending obliquely from the first portion and configured to follow the pharyngeal arc defined by the passage from the rear of the patient's mouth cavity through the oropharynx to a location adjacent the glottis. However, in fig. 19A Baildon teaches a hooked shaped tube with the second portion extending obliquely from the first portion and configured to follow the pharyngeal arc defined by the passage from the rear of the patient's mouth cavity through the oropharynx to a location adjacent the glottis. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Berman's shape with a hook shape, as taught by Baildon, to provide comfort to the user. The modified Berman discloses that the axis of the tube at the outlet is approximately perpendicular to the axis of the tube at the inlet (Fig. 19A Baildon).

Regarding claim 3, the modified Berman discloses that the first opening is defined by an end of the tube that is oblique to the axis of the tube (19A Baildon) so that a leading edge is adjacent the inside of the hook shaped formation (19A Baildon).

9. Claims 14, 15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berman in view of Friedman.

Regarding claim 14, in fig. 15 and 17 Berman discloses a unitary tube 10b having a passage there through; a locating flange 12b provided at a proximal end of a first portion of the tube to form, in combination with the first portion, at least part of a mouthpiece (fig. 32, Col. 4, ll. 5-9) defining an inlet to the passage, the flange adapted to locate adjacent an outer surface of the patient's mouth when the first portion of the tube extends into the mouth cavity (fig. 32), the tube having a second portion extending from the first portion, the second portion having a distal end which defines an outlet to the tube and which is adapted to extend to a location closely adjacent the base of the tongue (fig. 32). Berman is silent regarding that the device includes internal markings, however Friedman discloses a device (fig. 2 and 10) with internal markings (Page 3, para 30, ll. 13-17, Page 6, para 61). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Berman's internal walls with markings, as taught by Friedman, for the purpose of guiding an endoscope there through (Page 3, para 30, ll. 13-17, Page 6, para 61).

Regarding claims 15 and 18, the modified Berman discloses an internal surface relatively non reflective finish of polyethylene (Col. 4, ll. 62-63 Berman) and markings that form a contrast with the internal surface (Page 3, para 30, ll. 13-17, Page 6, para 61 Friedman).



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10. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berman/Friedman, as applied to claim 14 above, in further view of lund et al. (5,598,840).

Regarding claim 16, the modified Berman discloses markings, but is silent that they are made by way of printing. However, lund teaches the markings are made by way of printing (Col. 6, ll. 1-2). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Berman's markings with printed markings, for the purpose of making them more permanent.

11. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berman/Friedman, as applied to claims 14-15 above, in further view of Shikani et al. (5,762,638).

Regarding claim 17, the modified Berman discloses a low reflective finish, but is silent regarding that the low reflective finish is applied to the device as a coating. However, Shikani teaches anti-infective coatings that are applied to a catheter (Col. 8, ll. 18-22). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Berman's finish with an anti-infective coating, as taught by Shikani, for the purpose of preventing infection.

12. Claims 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berman/Elam, as applied to claim 1 above, in further view of Friedman and Fujikura et al (6,719,685).

Regarding claim 19, the modified Berman discloses a tube, but is silent regarding markings positioned on the interior surface of the tube which then extend to the first opening and outlet of the passage at the distal end of the tube. However, Friedman discloses a device (fig. 2 and 10) with internal markings (Page 3, para 30, ll. 13-17, Page 6, para 61). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Berman's internal walls with markings, as taught by Friedman, for the purpose of guiding an endoscope there through (Page 3, para 30, ll. 13-17, Page 6, para 61). The modified Berman is silent regarding that the markings are opposite the second opening. However, Fujikura teaches circular markings (fig. 18). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Berman's markings with circular markings, as taught by Fujikura, for the purpose of detecting the markings no matter the orientation of the endoscope.

Regarding claim 20, the modified Berman discloses that the markings are in the form of runway type markings configured to identify the central axis of that innermost surface of the device (any position identified by the endoscope identifies the central axis of the device).

Regarding claim 21, the modified Berman discloses that the markings are adapted to indicate proximity from the outlet (Page 3, para 30, ll. 13-17, Page 6, para 61 Friedman).

13. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berman, Elam, Friedman and Fujikura, as applied to claims 1 and 19 above, in further view of Aizawa (2002/0188174).

Regarding claim 22, the modified Berman discloses that the internal surface of the tube has makings, but is silent regarding that the peripheries of the openings have markings. However, Aizawa teaches an endoscope in fig. 15 with marker 114 around the periphery of hole 12a and probe 14b with matching marking 118 to identify the hole in which probe 14b should be delivered (page 13, para 286-289). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Berman's holes (74 Elam and distal end hole Berman) with markings matching sump tube and endotracheal tube markers, as taught by Aizawa, for the purpose of ensuring proper placement of suction and ventilation devices.

14. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berman/Elam, as applied to claim 1 above, in further view of West (2002/0162555).

Regarding claim 23, the modified Berman discloses that the mouthpiece includes a bite block (Col. 4, ll. 6-9), but is silent regarding that the mouthpiece includes means for providing rigidity that are adapted to prevent the patient biting down and blocking the passage. However, West teaches bite block 10 that is made of hard, medical grade plastic (Page 3, para 89). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Berman's bite block with a

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bite block of hard medical grade plastic, as taught by West, for the purpose of preventing obstruction of the tube.

15. Claims 24 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berman, Elam and West, as applied to claims 1 and 23 above, in further view of Baildon.

Regarding claim 24, the modified Berman is silent regarding that the tube portion is produced from a relatively soft, flexible resilient material. However, Baildon teaches a flexible oral airway (Col. 1, ll. 65-ll. Col. 2, ll. 6). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Berman's airway with a flexible airway, as taught by Baildon, for the purpose of providing comfort to a user. The modified Berman discloses that the means for providing rigidity in the mouthpiece include a reinforcing attachment of another more rigid material (10 West).

Regarding claim 28, the modified Berman is silent regarding that the device is manufactured from a biocompatible partially resilient material. However, Baildon teaches an oral airways manufactured from a biocompatible partially resilient material (Col. 3, ll. 1-7). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Berman's device with a biocompatible partially resilient material, as taught by Baildon, for the purpose of providing comfort to the user.

16. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berman/Elam, as applied to claim 1 above, in further view of Linderoth (6,588,426).

Regarding claim 26, the modified Berman discloses a flange, but is silent regarding that the flange includes openings for the attachment of securing ties. However, in fig. 1-2 Linderoth teaches openings in a tracheal flange. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Berman's flange with openings, as taught by Linderoth, for the purpose of securing the device to the user.

17. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berman/Elam, as applied to claim 1 above, in further view of Alfery (6,729,325).

Regarding claim 27, the modified Berman discloses a mouthpiece, but is silent regarding that the mouthpiece includes a standard connector to enable connection to an anaesthetic breathing circuit if required. However, Alfery teaches an oral airway with an anesthetic adaptor (Col. 6, ll. 42-46, 562). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Berman's mouthpiece with an adaptor, as taught by Alfery, for the purpose of providing anesthetic to a user.

18. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berman/Elam, as applied to claim 1 above, in further view of Baildon and Sato (5,743,258).

Regarding claim 29, the modified Berman is silent regarding that the device is hook shaped. However, in fig. 19A Baildon teaches a hooked shaped tube. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Berman's shape with a hook shape, as taught by Baildon, to provide comfort to the user. The modified Berman is silent regarding that the device is formed from a biocompatible shape memory alloy whereby the device is flexible at room temperature, but conforms to a hook formation when heated to a predetermined temperature consistent with that expected in the patient's airway. However, Sato teaches an airway tube of shape memory alloy that conforms to a shape when heated to 36 degrees Celsius (Col. 11-12, claim 8). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Berman's airway with shape memory alloy conforming to the modified Berman's hook shape, as taught by Sato, for the purpose of providing comfort to a user.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Milo et al. (5,427,107) to reflective and non reflective surfaces for orientation and Mikus et al. (6,164,305) to graduations located by an endoscope. Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHEL YOUNG whose telephone number is (571)270-1481. The examiner can normally be reached on mon-fri 8 am - 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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